Submission of this application to the DSHS IRB constitutes a request for review and approval of: 1) research involving the use of human subjects and/or 2) request for release of DSHS data, including personal (protected) health information.

Principal Investigator/Requestor:
(List other Investigators, as needed, in Project Description)

Name: _____

Address: _____

_____

_____

Phone: _____

E-Mail: _____

Student Investigator/Requestor: ☐ Yes ☐ No

DSHS Program Contact:
(DSHS employee; contact with a DSHS Program is required prior to submission)

Name: _____

Address: _____

_____

Program Area: _____

Phone: _____

E-Mail: _____

Application for review of:
(Check all that apply – application may be for both research and data request combined)

☐ Research involving human subjects

The human subjects regulations (45 CFR Part 46) define research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)]. A human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information" [45 CFR 46.102(f)].

☐ Request for the release of data, including personal (protected) health information

Specific DSHS Program data requiring approval by an independent board to be released or individually identifiable health information about an individual, including demographic information, which relates to the individual's past, present, or future physical or mental health condition, provision of health care, or payment for the provision of health care [protected health information (PHI)].

Submission Type: Start Date: ___/___/___ End Date: ___/___/___

New Application ☐ Request Review: Exempt ☐ Expedited ☐

Re-submission ☐ DSHS IRB #:

Renewal ☐ DSHS IRB #:

Amendment ☐ DSHS IRB #:

Submission Title:

DSHS IRB #:_____

For Official Use Only

Required Subject Characteristics (Check all that apply)

Age: ☐17 years and under ☐18 years and older

Vulnerable Categories: **(If subjects must be members of a vulnerable category, check "Yes." Otherwise, check "No.")**

Elderly/Aged	☐No	☐Yes				
Fetuses	☐No	☐Yes				
Pregnant Women	☐No	☐Yes				
Prisoners	☐No	☐Yes				
Impaired	☐No	☐Yes	If yes,	☐Physically	☐Cognitively	☐ Both

Funding Source (List as appropriate)

Federal _____

State _____

Other _____

Review by Other Institutional Review Board (ethic/research/science boards/panels)

(Name)	(Telephone Number)	(Review Date)
(Name)	(Telephone Number)	(Review Date)

Signature: Principal Investigator/Requestor **Date Signed**

Signature: DSHS Program Contact **Date Signed**

Submit the following documents for review:

- ➔ DSHS IRB Forms:
  - Application Form (Page 1-2)
  - Exemption Request form or Expedited Review Request form – as appropriate
- ➔ Project Description
- ➔ Appendices

➔ **NOTE:** For Continuation Review (Renewal), see the Application Submission Manual

Project Description should provide a clear statement of the work to be undertaken and must include:

A **Summary/synopsis** of the research project is a critical part of the IRB submission because it introduces the reviewers to the study to get a quick understanding of just what is being proposed. The summary of study objectives should be written as if you were trying to give an overview of your research to someone who is not a scientist or medical professional. It is not necessary to include a complete description of the study design in this portion of the submission; rather, give a general sense of the strategy and/or techniques involved.

B **Research Plan:**

1-Introduction/Background – should contain the history of the disease and current treatment. References to pertinent studies and the rationale for the proposed modalities should also be presented.

2-Objectives/Specific Aims – The questions to be addressed by this study and the end-points should be stated.

C **Subject Selection:**

1-Study Population – this section should describe the population under study, the potential sources and the number and sample size methodology used to determine the proposed sample.

2-Eligibility Criteria – inclusion criteria, such as: sites, stage of disease/histology, age (lower and upper limits should be stated), performance status, laboratory values, and other evaluations as applicable, etc. Explain the rationale for the use of special classes of subjects such as fetuses, pregnant women, women of childbearing potential, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.

3-Ineligibility Criteria – exclusion criteria, such as: prior treatment, prior other diseases, infection, hematologic, and other values that preclude entry into study.

4-Recruitment/Registration – this section should describe how potential subjects will be identified and contacted - the 'where and when to call' and the information to provided to the subject. Advertisements, flyers and any other materials that will be used to recruit subjects must be reviewed and approved by the IRB prior to their use.

D **Protocol Details:**

1-Research Design and Methods – such as: intervention therapy (e.g. surgery, drug, radiation, etc.), exposure (e.g. media campaign, curriculum, best practice, etc.). This section should describe the type of research to be conducted (e.g. experimental, quasi-experimental, case study, evaluation, outcome, etc.).

2-Subject Assessment – this section should contain the requirements for each assessment to be conducted. The studies to be done and the follow-up times should also be detailed in either outline or graphic format.

3- Data/PHI – this section should contain a list of all data items [for the release of DSHS data, specific information on the use of individual data fields may be required as defined by DSHS program area], including forms, and the specified timetable for collection. Include a discussion of confidentiality safeguards including the specific steps you will take to a) provide privacy during interviews, b) keep forms secure, c) keep data confidential, d) prevent release or publication of identifying data, and e) retain and ultimately dispose of records. Specifically describe all health information that the project will be using and/or requesting (e.g., personal identification information; billing records; medical history; physical findings from exams; lab, pathology and radiology results; results of MRIs, X-Rays, blood test and similar tests; PHI previously collected for research purposes; answers to questionnaires/interviews, etc.). If you will use the entire medical file, then you must mention this fact specifically.

4-Statistical Design & Analysis – this section should include a discussion of the end point(s), the difference expected, and the analytical methods to be employed to detect the difference.

5-Informed Consent Form – this section should contain all forms to be used, each form should be clearly identified and dated.

6-Risks/Benefits – this section should include procedures for protecting against or minimizing risks, the potential benefits to be gained by the subjects, and the benefits that may accrue to society in general because of the planned work. Describe any potential risks--physical, psychological, social, legal, or other--and assess their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used. Where relevant, describe arrangements for providing medical treatment if needed.

7-Student Investigator/Requestor – if you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member. The student's committee must approve thesis and dissertation proposals before to approval by the IRB.

Appendices

This section should include documentation and material - such as: questionnaires, surveys and other assessment tools; brochures, media flyers, etc.; certificates of human subject training; letters of support/approval from study sites or other IRB, etc.

Funding – if the study will be funded by a federal agency, please include a copy of the full grant proposal or a detailed summary

Do not include this page in DSHS IRB Application submission

Institutional Review Board
Department of State Health Services

Submission Address

Send submission to: **Department of State Health Services**
Institutional Review Board
1100 West 49th Street
Austin, Texas 78756-3199

Meeting Schedule

The IRB meets on the third Thursday of each month, in Austin, beginning at 1:00 p.m. Open meetings will be posted in the Federal Register and on the IRB's web site http://www.DSHS.state.tx.us/irb/default.htm

Submission Deadline

*Your application must be received **in the IRB office** before the first working day of the month* to be eligible for review at that months meeting. Those received on or after the first working day of the month will be scheduled for the following month, unless they can be exempted or expedited.

Application Submission Checklist

Is your application complete? (Every item needs a response). Does it include:

- ☐ Principal Investigator/Requestor name, complete mailing address, telephone number, including extension if applicable, and e-mail
- ☐ Student Investigator/Requestor question answered
- ☐ DSHS Program Contact name, complete mailing address, telephone number, including extension, and e-mail
- ☐ Application for review designated as Research, Release of Data, or Both
- ☐ Submission Type designated, including start and end dates
- ☐ Submission Title section completed
- ☐ Age groups designated
- ☐ **Required** Vulnerable Categories clarified
- ☐ Funding Source
- ☐ Other Boards or Panels that reviewed the submission
- ☐ Principal Investigator/Requestor's signature and date of signature
- ☐ DSHS Program Contact's signature and date of signature
- ☐ Program Description (see previous page)
- ☐ Questionnaires, surveys, and other assessment tools; brochures, media flyers, etc., if used in the study
- ☐ Documentation that the Principal Investigator completed a course in human subject protection
- ☐ Letters of support/approval from study sites, data sources, or other IRBs, if appropriate
- ☐ Appropriate number of copies made
  - ☐ One signed original and 7 copies (copies double-sided) for a full IRB review at the next convened meeting.
  - ☐ One signed original and one copy (copy double-sided) of the submission if you are requesting either an expedited review or an exemption. The submission must include either the signed expedited review checklist and/or the exemption request checklist, as appropriate.

<u>Do not</u> include this page in DSHS IRB Application submission